REMARKS

The Office Action mailed February 10, 2003, has been received and reviewed. Claims 1, 2, 4-16, 22 and 25 are currently pending in the application. Claims 1, 4, 6, 8-16, 22 and 25 currently stand rejected. All amendments are made without prejudice or disclaimer. Applicants respectfully request reconsideration of the application as amended herein and in view of the remarks presented below.

I. Priority

The priority claim in the first sentence of the specification has been amended to address the Examiner's concerns relating to priority. Reconsideration of the applicant's priority claim is respectfully requested.

II. The Specification

The specification is objected to for the following informalities: the description of the drawings is after the detailed description of the invention. As suggested by the Examiner, the applicants have amended the specification to delete the description of the drawings following the detailed description of the invention. The applicants have added the description of the drawings and new headings before the detailed description. The paragraphs added are substantially the same as the deleted paragraphs, therefore, no new matter is added. Reconsideration and withdrawal of the objection is respectfully requested.

III. 35 U.S.C. § 101

Claims 1, 4, 6, 8, 12 and 13 stand rejected under 35 U.S.C. § 101 as allegedly drawn to non-statutory subject matter due to the alleged absence of a distinction over naturally occurring CAV. The applicants have amended independent claims 1, 2, 4 and 5 to recite a recombinant gene delivery vehicle, as suggested by the Examiner. Reconsideration and withdrawal of the rejection is respectfully requested.

IV. 35 U.S.C. § 112, first paragraph

Claims 22 and 25 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement commensurate with the scope of the claims. The applicants respectfully

disagree with the Examiner's position that the specification does not enable a person of ordinary skill in the art to administer the gene delivery vehicle to sites other than directly to the tumor. The applicants submit that a person of ordinary skill in the art, using the guidance of the specification, would have been enabled to induce apoptosis other than by directly administering to the tumor. For example, the tropism of the gene delivery vehicle may be used to target specific tissues. However, to expedite prosecution of the application, the applicants have amended claims 22 and 25 to recite "administering to the tumor," which the Examiner has acknowledged to be enabled (Office Communication at pages 10-11). Reconsideration and withdrawal of the rejection is respectfully requested.

V. 35 U.S.C. § 102

Claims 1, 4, 6, 8, 12-14, 22, 23, 25 and 26 stand rejected as allegedly being anticipated by Noteborn *et al.* Claims 1, 4, 6, 8 and 12 stand rejected "under 35 U.S.C. 102(b) as being anticipated" by Yuasa *et al.* in view of Noteborn. For the purposes of this response, the applicants interpret the rejection of claims 1, 4, 6, 8 and 12 to be under 35 U.S.C. § 102, based on inherent discloser in Yuasa.

The Office asserts that Noteborn teaches that CAV virus comprises three partially overlapping reading frames, a targeting molecule (the capsid) and infection of chicken lymphoblastoid cell lines. However, the claims read on a "recombinant gene delivery vehicle," which consists of portions of different DNA molecules. For example, *see* page 6, line 34 to page 7, line 12 of the specification. In the Noteborn reference, under the heading "CPE of c-DNA," CAV DNA is circularized by self-ligation and transfected into MDCC-MSB1 and 1104-X-5 cells (page 3135). Thus, the DNA molecule transfected into lymphoblastoid cells is not a recombinant gene delivery vehicle.

Furthermore, the experiment described under the heading "pathogenic effect of c-CAV in chickens" (page 3135) utilized CAV virus particles, which are not a "recombinant" gene delivery vehicle. Therefore, Noteborn does not anticipate the claims. Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1, 4, 6, 8 and 12 stand rejected as allegedly anticipated by Yuasa. Yuasa, like Noteborn, does not disclose a "recombinant gene delivery vehicle" as claimed. Reconsideration and withdrawal of the rejection is thus respectfully requested.

VI. Double Patenting

Claims 22 and 25 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-7 of U.S. Patent 5,981,502. In addition, Claims 1, 4, 6, 8, 22 and 25 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 23-29, 31-33 and 37-41 of U.S. Patent 6,162,461. Strictly to expedite prosecution of the application, the applicants offer to submit the appropriate terminal disclaimer for U.S. Patents 6,162,461 and/or 5,981,502 when claims 1, 4, 6, 8, 22 or 25 are found allowable.

However, the applicants point out that claims 23-29, 31-33 and 37-41 of U.S. Patent 6,162,461 are directed to a process of treating tumors using nucleic acids (Group VI), as per the restriction requirement issued in the Office Action, mailed April 1, 1997, in application serial number 08/482,161, now U.S. Patent 6,162,461. As noted in the restriction requirement, Group V, claims drawn to nucleic acids, vectors and host cells, are patentably distinct from Group VI. Reconsideration and withdrawal of the rejections is respectfully requested.

Claims 1, 7, 8, 9, 10, 11 and 14-16 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 23-29, 31-33 and 37-41 of U.S. Patent 6,162,461 in view of Mason *et al.* (U.S. Patent 5,643,770). The applicants note that "[o]ne significant difference [between obviousness-type double patenting and § 103] is that a double patenting rejection must rely on a comparison with the claims ...." MPEP § 804(III)(emphasis added). Mason *et al.* claims a retroviral vector particle expressing a complement inhibitor activity, wherein the retroviral vector article is substantially protected from inactivation upon exposure to body fluids containing complement. Thus, the applicants submit that Mason *et al.* does not claim the production of a retroviral packaging cell line using PA-317 or replication defective retroviral vectors. Therefore, Masson does not rectify the deficiencies of the '461 claims or render obvious the claims of the current application. In addition, Mason *et al.*

is not commonly owned and, according to chart II-B (MPEP § 804), is inapplicable to a double patenting rejection.

The applicants also note that claim 7 includes the translation initiation sequence, which is not disclosed in any of the claims found in U.S. Patents 6,162,461 and 5,643,770. Reconsideration and withdrawal of the rejection is respectfully requested. However, in order to expedite prosecution of the current application, the applicants offer to file an appropriate terminal disclaimer for U.S. Patent 6,162,461, should claims 1, 8, 9, 10, 11 and 14-16 be found allowable. Reconsideration and withdrawal of the rejection is respectfully requested.

VII. Claims 2, 5 and 7

Claims 2, 5 and 7 are objected to because they depend on rejected claims, but would be allowable if rewritten in independent form. These claims have been rewritten into independent form as suggested by the Examiner and should be allowable. Reconsideration and withdrawal of the objection is respectfully requested.

CONCLUSION

In the event questions remain after consideration of these remarks and amendments, the Office is kindly requested to contact applicant's attorney at the number given below.

Respectfully submitted,

G. Scott Dorland, Ph.D.
Registration No. 51,622
Attorney for Applicants
TRASKBRITT, P.C.
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

Date: June 25, 2003
GSD/gsd/bv

\\Traskbritt1\Shared\DOCS\2906-4999US\40717.doc